DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
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Minneapolis, MN 55401
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April 30, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 22

Suzanne Weinstein
President/Owner
Worldwide Fish & Seafoods, Inc.
2330 Minnehaha Avenue South
Minneapolis, Minnesota 55404

Dear Ms. Weinstein:

On December 4, 5, and 12, 2003, we inspected your seafood processing facility located in Minneapolis, Minnesota. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your smoked salmon is adulterated in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act and its implementing regulations through links in FDA's home page at *www.fda.gov.*

The deviations noted on the issued FDA-483, Inspectional Observations, of most concern which cause your product to be adulterated are as follows:

1. You must have a HACCP plan that, at a minimum, lists the Critical Limits that must be met to comply with 21 CFR 123.6(c)(3). A Critical Limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point (CCP) to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for fresh ready to eat seafood products that includes

vacuum packed smoked salmon, lists a Critical Limit at the receiving CCP that is not adequate control pathogen growth.

Specifically, your Critical Limit of "Product must be at [redacted]F" is not adequate to control pathogen growth and toxin formation during transport of the refrigerated vacuum packaged product. FDA considers records that show that the product was held at or below 40°F throughout transit to be an adequate critical limit at receipt. This can be accomplished by monitoring the internal temperature of the product or the ambient temperature in the carrier(s) throughout the transit period.

We note that your plan also lists the following alternative Critical Limit: "product is buried in adequate ice or gel refrigeration." Although this Critical Limit can be adequate for the control of pathogens during product transport if certain controls are in place, your procedures are not adequate. Appropriate implementation of this Critical Limit requires proper monitoring of a sufficient number of containers to represent all of the product received and appropriate record keeping. It also requires an appropriate verification procedure to ensure that this measure is providing adequate control of product temperature. These elements were not employed by your firm or included in your HACCP plan.

2. You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a)(2). However, your firm's HACCP plan for fresh ready to eat seafood products that includes vacuum packed smoked salmon, lists verification procedures at the cooler storage CCP that are not adequate to control the hazard of pathogen growth and toxin formation. FDA recommends that the cooler temperature monitoring instrument be verified by checking for accuracy of the monitoring equipment at least once per day. During the inspection, you acknowledged receiving only weekly temperature control reports from the outside monitoring firm, while your HACCP plan calls for daily record reviews for verification. You must implement your HACCP plan as written.

3. You must implement the record keeping system that you listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations of the "level of ice or gel refrigeration" on the "Receiving invoice" at the receiving CCP to control "Bacterial pathogen growth" as listed in your HACCP plan for fresh ready to eat seafood products that includes vacuum packed Smoked Salmon.

4. Since you chose to include Corrective Actions in your HACCP plan, your described Corrective Actions must be appropriate to comply with 21 CFR

123.7(b). However, your Corrective Action Plan provides that you will "Conduct sensory evaluation and reject unacceptable product" for fresh ready to eat seafood products, that includes vacuum packed smoked salmon, at the receiving and storage CCP is not adequate to control the hazard of pathogen growth and toxin formation. Pathogens and their toxins cannot reliably be detected by sensory means. FDA recommends that you analyze the time/temperature exposure of the product to determine the potential for pathogen growth and toxin formation (*FDA Fish and Fishery Products Hazards and Controls Guidance, Third Edition*, Appendix 4, Bacterial Pathogen Growth and Inactivation) before accepting or rejecting it. The written Corrective Action Plan should also include steps to be taken to ensure that the cause of the critical limit deviation is corrected [21 CFR 123.7(b)(2)], but this is not reflected in your plan at the receiving or cooler storage CCP.

5. For refrigerated products, you must retain records at the processing facility for at least one year after the date they were prepared to comply with 21 CFR 123.9(b)(1). However, your firm's contracted storage temperature monitoring records for refrigerated vacuum packed smoked salmon were not retained at your processing facility and were not available for official review [21 CFR 123.9(c)].

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and all implementing regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

For information regarding recommended control strategies for pathogen growth and toxin formation, please refer to FDA's *Fish and Fishery Products Hazards and Controls Guidance, Third Edition*, Chapter 12 (Pathogen Growth & Toxin Formation (Other than Clostridium botulinum) as a Result of Time/Temperature Abuse), found *at http://www.cfsan.fda.gov/~comm/haccp4.html.*

Please send your reply to Compliance Officer Tyra S. Wisecup at the address in the letterhead. If you have questions regarding any issue in this letter, please contact Ms. Wisecup at (612) 758-7114.

Sincerely,

W. Charles Becoat
Director
Minneapolis District